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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,028

05/17/2005

Rajesh R Naik

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EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/507,028

Applicant(s)

NAIK ET AL.

Examiner

Amber D. Steele

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 30, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 and 20-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 19 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/11/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-32 are currently pending.

Claims 1-8, 19, and 32 are currently under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1-8) in the reply filed on October 30, 2006 is acknowledged. The traversal is on the ground(s) that Hefti does not teach peptide that can bind a target inorganic material. This is not found persuasive because Hefti teaches peptides and proteins that can bind a conductive layer which includes gold, copper, silver, tin, etc. (e.g. inorganic material). However, upon further consideration the restriction between Groups I (claims 1-8), LVIII (claim 19), and CXX (claim 32) is withdrawn. The restriction requirement among all other groups is maintained.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 9-18 and 20-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 30, 2006.

Priority

4. The present application claims priority as a national stage application (371) of PCT/US03/07617 filed March 13, 2003 which claims benefit of provisional applications 60/363,551 filed March 13, 2002 and 60/369,330 filed April 3, 2002.

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, provisional Application Nos. 60/363,551 and 60/369,330, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application for 60/363,551 (filed March 13, 2002) is a six page non-patent literature document (Naik, Brott, Clarson, and Stone; Journal of Nanoscience and Nanotechnology 2(1): 95-100, 2002) wherein a commercially available 12 amino acid phage peptide display library (New England Biolabs®) is screened for binding to silica. The provisional application for 60/369,330 (filed April 3, 2002) is a one page document disclosing three peptide sequences that bind to silver (Ag3: AYSSGAPPMPPF, Ag4: NPSSLFRYLPSD, and Ag5: SLATQPPRTPPV) and thus does not disclose the presently claimed method. Therefore, claims 1-5, 19, and 32 with regard to the species of silica as the inorganic material only has priority to March 13, 2002. All other methods utilizing any other inorganic materials have a priority date of March 13, 2003 (filing date for PCT/US03/07617).

Information Disclosure Statement

6. The information disclosure statement filed January 11, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. A copy of JP 04346999 was not provided.

7. The information disclosure statement filed January 11, 2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. A translation or a concise explanation of the relevance of DE 19819843 was not provided.

Drawings

8. The drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 CFR §1.58(a) and §1.83(a).

Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 CFR §§1.821-1.825 will be published as part of the patent.

Applicants should amend the specification to delete any figures/drawings which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (e.g. as SEQ ID NOs) and should further amend the specification accordingly to reflect the replacement of the drawing/figure by the appropriate SEQ ID NO:. If the figures

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provide additional information not provided in the sequence listing then proper SEQ ID NOs: should be provided for the sequences.

Appropriate correction is required.

Specification

9. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

10. The disclosure is objected to because of the following informalities: Table 1 requires SEQ ID NOs:, page 18 contains the symbol □ embedded in chemical formulas.

Appropriate correction is required.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-8, 19, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 USC 112, first paragraph "Written Description" requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a **written description** rejection.

Claim 1 is drawn to a method for identifying peptides that bind an inorganic material comprising (a) incubating a combinatorial phage peptide display library with an inorganic target material, (b) eluting the library to collect target bound phage, (c) isolating the nucleic acid of the phage, and (d) sequencing the nucleic acid. The invention as claimed encompasses all known peptides and all potential peptides since virtually any peptide can be phage displayed. In addition, the invention as claimed encompasses all known and all potential inorganic target materials. The claimed invention states that the phage-displayed peptide must bind an inorganic target material. However, the claimed invention does not include any structural information regarding the peptide or the inorganic material. In addition, the claimed invention does not include any structural information regarding how a phage-displayed peptide binding to an inorganic target material (e.g. non-specific binding encompassed by the presently claimed method, etc.).

The specification teaches phage-displayed peptides that bind to silica (8 peptides), silver (3 peptides), germanium (1 peptide), cobalt oxide (27 peptides), and iron oxide (16 peptides; please refer to pages 11-13 and the sequence listing). However, the specification is silent on peptides that bind aluminum, antimony, beryllium, cadmium, copper, gold, iron, lead, selenium, palladium, platinum, zinc, and oxides thereof or radioactive targets, radioactive cobalt, or

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radioactive uranium (e.g. mere suggestion provided). Therefore, one skilled in the relevant art would not reasonably conclude that the Applicants had possession of the entire scope of the invention as claimed. While one of skill in the art may conclude that the applicants had possession of a method to screen for peptides that bind to silica, silver, germanium, cobalt oxide, and iron oxide, one of skill in the art would not conclude that the applicants had possession of a phage-display library to screen for aluminum, antimony, beryllium, cadmium, copper, gold, iron, lead, selenium, palladium, platinum, zinc, and oxides thereof or radioactive targets, radioactive cobalt, or radioactive uranium. In addition, it is noted that the silica binding peptides do not appear to have a common core structure, the silver binding peptides do not appear to have a common core structure, the cobalt oxide binding peptides do not appear to have a common core structure, and the iron oxide binding peptides do not appear to have a common core structure. Thus, it is not clear if applicants were in possession of a requisite number of species of the genus to have adequate written description for silica, silver, germanium, cobalt oxide, or iron oxide binding peptides.

See Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was *in possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116.).

With the exception of a method utilizing a phage display library comprising the peptides of SEQ ID NOs: 1-55 as disclosed by the specification, the skilled artisan cannot envision that

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the applicants had possession of the entire scope of the method of present claim 1. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class wherein the specification provided only the bovine sequence.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-8, 19, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sharma U.S. Patent 6,027,711 issued February 22, 2000.

The presently claimed invention is drawn to a method for identifying peptides that bind an inorganic material comprising (a) incubating a combinatorial phage peptide display library with an inorganic target material, (b) eluting the library to collect target bound phage, (c) isolating the nucleic acid of the phage, and (d) sequencing the nucleic acid.

For present claims 1, 19, and 32, Sharma teaches a method for identifying peptides that bind metals and other ligands (e.g. inorganic material; stable) comprising screening libraries which may be phage displayed via (a) incubating a peptide library with a metal and/or an additional ligand, (b) eluting the library to collect target bound phage, (c) isolating the nucleic

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acid of the phage, and (d) sequencing the nucleic acid (please refer to entire specification particularly abstract, Figures 1B, 1C, column 4, lines 57-67; column 5, lines 1-48; column 6, lines 29-67; column 7, lines 1-30; column 9, lines 15-40; columns 10-18; column 22, lines 62-67; column 23, lines 17-35 and 60-67; columns 24-29; column 31, lines 22-67; column 32, lines 1-23; column 40, lines 25-67; column 41, lines 1-51; Examples 1-74).

For present claim 2, Sharma teaches phage display of peptides (please refer to column 7, lines 16-30).

For present claim 3, Sharma teaches screening of libraries (e.g. repeating; please refer to columns 17-18; column 40, lines 60-67; column 41, lines 1-51).

For present claim 4, Sharma teaches chelating and binding of metals (e.g. precipitation or deposition; please refer to columns 10-18; column 22, lines 63-67).

For present claim 5, Sharma teaches inorganic metals including silver, cobalt, and iron (please refer to column 10, lines 53-57; column 11, lines 35-42; column 23, lines 60-67; column 24, lines 1-24; column 31, lines 22-52; column 40, lines 45-48).

For present claim 6, Sharma teaches inorganic metals including antimony, cadmium, copper, gold, lead, selenium, palladium, platinum, and zinc (please refer to column 4, lines 57-67; column 5, lines 1-48; column 10, lines 53-57; column 11, lines 35-42; column 23, lines 60-67; column 24, lines 1-24; column 31, lines 22-52; column 40, lines 45-48).

For present claim 7, Sharma teaches radioactive metals (please refer to column 11, lines 35-42; column 23, lines 60-67; column 24, lines 1-24; column 32, lines 5-6).

For present claim 8, Sharma teaches radioactive cobalt (please refer to column 11, lines 35-42; column 23, lines 60-67; column 24, lines 1-24).

Therefore, the presently claimed invention is anticipated by the teachings of Sharma.

16. Claims 1-7, 19, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kay et al. U.S. Patent 5498538 issued March 12, 1996.

The presently claimed invention is drawn to a method for identifying peptides that bind an inorganic material comprising (a) incubating a combinatorial phage peptide display library with an inorganic target material, (b) eluting the library to collect target bound phage, (c) isolating the nucleic acid of the phage, and (d) sequencing the nucleic acid.

For present claims 1, 19, and 32, Kay et al. teach a method for identifying peptides (TSARs) that bind an inorganic material including stable materials (e.g. zinc and copper) comprising (a) incubating a combinatorial phage peptide display library with an inorganic target material, (b) eluting the library to collect target bound phage, (c) isolating the nucleic acid of the phage, and (d) sequencing the nucleic acid (please refer to abstract; Figures 1B, 1C, 1D, 1E, 1F, 5D, 7; column 5, lines 1-45; column 6, lines 27-67; column 7, lines 1-3; column 8, lines 46-57; Brief Description of the Figures; column 11, lines 57-67; column 1-6; column 21, lines 18-45; column 48, lines 19-21; section 5.1.2.2, 5.1.3, 5.2, 5.3, 6-6.3.2, 7-7.3; Tables 2, 3; claims 1-3, 6, 7, 9, 10, 13, 14, 17, 20, 21, 24, 25, 26).

For present claim 2, Kay et al. teach phage display of TSARs including peptides (please refer to Figures 5, 10, 14; column 9, lines 47-61; column 10, lines 14-23 and 63-67; column 20, lines 60-67; column 21, lines 18-45; column 22, lines 40-67; column 23, lines 1-35).

For present claim 3, Kay et al. teach repeating screening steps (please refer to Figure 7; section 5.2 particularly column 30, lines 34-36; section 7.1).

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For present claim 4, Kay et al. teach eluting, binding, etc. of peptides to inorganic targets (e.g. deposition or precipitation; please refer to section 5.2; section 7.1).

For present claim 5, Kay et al. teach utilizing silica columns to capture phage-displayed peptides wherein non-specific binding to silica can occur (please refer to column 30, lines 37-44).

For present claim 6, Kay et al. teach copper and zinc (please refer to column 19, lines 10-53; section 7.3; Tables 2, 3).

For present claim 7, Kay et al. teach radioactive inorganic targets (please refer to column 35, lines 14-26).

Therefore, the presently claimed invention is anticipated by the teachings of Kay et al.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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18. Claims 1-8, 19, and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 19, and 32 of copending Application No. 11/045,488. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed method and the method of 11/045,488 claim a method for identifying peptides that bind an inorganic material comprising (a) incubating a combinatorial phage peptide display library with an inorganic target material, (b) eluting the library to collect target bound phage, (c) isolating the nucleic acid of the phage, and (d) sequencing the nucleic acid.

For present claims 1, 19, and 32, 11/045,488 claims a method for identifying peptides that bind an inorganic material comprising (a) incubating a combinatorial phage peptide display library with an inorganic target material, (b) eluting the library to collect target bound phage, (c) isolating the nucleic acid of the phage, (c1) amplifying the nucleic acid via PCR, and (d) sequencing the nucleic acid (please refer to claims 1, 25, 31).

For present claim 2, 11/045,488 claims expressing the peptide (please refer to claim 3).

For present claim 3, 11/045,488 claims repeating steps of the method (please refer to claim 4).

For present claim 4, 11/045,488 claims peptide capable of catalyzing the deposition, precipitation, or growth of the inorganic material (please refer to claim 5).

For present claims 5-6, 11/045,488 claims silver, gold, platinum, cobalt, silica, iron, zinc, palladium, germanium, aluminum, antimony, beryllium, cadmium, copper, lead, selenium, cobalt, and oxides thereof (please refer to claim 6).

For present claim 7, 11/045,488 claims radioactive material (please refer to claim 7).

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For present claim 8, 11/045,488 claims radioactive cobalt and uranium (please refer to claim 8).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

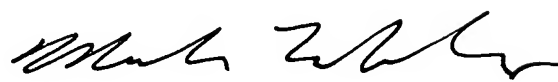
Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
January 10, 2007



MARK L. SHIBUYA
PRIMARY EXAMINER